REMARKS

This application has been carefully reviewed in light of the Advisory Action dated November 24, 2006. Claims 1, 3, 5, 7, 9, 11, 13 and 15 remain in this application. Claim 1 is the independent Claim. Claim 1 has been amended. Claims 2, 4, 6, 8, 10, 12, 14 and 16 have been canceled without prejudice. It is believed that no new matter is involved in the amendments or arguments presented herein. Reconsideration and entrance of the amendment in the application are respectfully requested.

Art-Based Rejections

Claims 1-4 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,833,644 (Zadno-Azizi) in view of U.S. Patent No. 5,667,521 (Keown); Claims 5-8 were rejected under § 103(a) over Zadno-Azizi in view of Keown and further in view of U.S. Patent No. 5,308,342 (Sepetka); Claims 9-12 were rejected under § 103(a) over Zadno-Azizi in view of Keown, and further in view of U.S. Patent No. 5,536,248 (Weaver); Claims 13-16 were rejected under § 103(a) over Zadno-Azizi in view of Keown and further in view of Sepetka.

The Keown Reference

Keown is directed to a rapid exchange catheter 5 with a separate distal tip 45 that is attached to the end tip of the catheter 5. The catheter 5 contains a core wire 10 that provides push to the distal tip 45 that is attached to the end of catheter 5. This separate distal tip 45 contains a guide wire lumen 50. The distal tip 45 with the guidewire lumen 50 can be implemented with a variety of shapes as shown in Figs. 9A to 9E that fit on at end tip of the catheter 5. Keown also discloses that the

guidewire lumen 50 contained in the distal tip 45 can be 0.75 cm. (*See, Keown, Abstract; col. 5, lines 19-27*; col. 5, lines 50-62, col. 7, lines 38-57)

The Sepetka et al. Reference

Sepetka is directed to a catheter composed of an outer coaxial tube of relatively high flexibility and three tandemly disposed inner coaxial tube segments that vary in stiffness. (*See, Sepetka, col. 1 lines 67- 68; col. 2, lines 57- 62; Fig. 2*)

The Weaver et al. Reference

Weaver is directed to a method of electrosurgically obtaining access to the biliary tree of a patient and visualizing a duct thereof using a catheter having at least a first lumen and a second lumen. Weaver in Fig. 6 discloses a catheter having two lumens 32 and 34 on a distal end. Both the two lumens are shown to be connected from a proximal end to a distal end of the catheter. (*See, Weaver, Abstract, Fig. 6, col. 10, lines 1 - 5*)

The Zadno-Azizi et al. Reference

Zadno-Azizi et al. is directed to a catheter 280 comprising an elongated shaft 282 with a lumen 284 for aspiration. At the distal end 288 of elongated shaft 282, a separate inner catheter lumen 286 is positioned adjacent the main aspiration lumen 284. This inner catheter or guidewire lumen 286 can be as short as 5 cm, but can extend to 30 cm or larger in proximal direction. (*See Zadno-Azizi, col. 11, line 58 – col. 12, line 1; Fig. 14-15)*

The Claims are Patentable Over the Cited References

The present application is generally directed to and aspiration catheter.

As defined by amended independent Claim 1, an aspiration catheter includes a main shaft with an aspiration lumen disposed therein. The aspiration lumen extends from the proximal end to the distal end of the main shaft. A guidewire shaft with a guidewire lumen disposed therein. The guidewire lumen follows a guidewire. The guidewire shaft is positioned at the distal end of the main shaft. A hub is located at the proximal end of the main shaft. The tip of the main shaft is obliquely cut. The distal end of the guidewire shaft is positioned at the distal end of the main shaft or it protrudes from the distal end of the main shaft in the distal direction. The relationships 2 mm $\leq$ L1 $\leq$ 10 mm, 1 mm $\leq$ L2 $\leq$ 15 mm, 0.5 $\leq$ L2/L1 and L2 - L1 $\leq$ 5 mm are satisfied, where L1 is the length of the obliquely cut portion of the main shaft in the longitudinal direction of the catheter, and L2 is the length from the proximal end of the guidewire shaft to the distal end of the main shaft. The main shaft includes two shafts of a proximal shaft and a distal shaft. The distal shaft is composed of a material having a lower modulus compared with the proximal shaft. The material for the distal shaft includes polyolefins, polyamides, polyesters, polyurethanes, polyolefin elastomers, polyamide elastomers, polyester elastomers, and polyurethane elastomers. The material for the proximal shaft includes polyimides, polyamide-imides, polyether ether ketones, stainless steel, and nickel-titanium alloys.

The applied references do not disclose or suggest the above features of the present application as defined by amended independent Claim 1. In particular the applied references do not disclose or suggest, "the relationships 2 mm $\leq$ L1 $\leq$10 mm, 1 mm $\leq$ L2 $\leq$ 15 mm, 0.5 $\leq$ L2/L1 and L2 - L1 $\leq$ 5 mm are satisfied...wherein... L2 is the length from the proximal end of the guidewire shaft to the distal end of the main shaft", as required by amended independent Claim 1.

It is an aspect of the present Application a guidewire shaft 303/403 has a guidewire lumen. The guidewire shaft is disposed at the distal end of a main shaft,

where the distil tip of the main shaft has been cut obliquely. The distal end of the guidewire lumen can be positioned at the distal tip of the main shaft 301 as depicted in Fig. 3 or can extend past the main shaft 401 as depicted in Fig. 4. However, in both cases the length L2 is defined as the portion of the guidewire shaft 303/403 that is attached to the main shaft 301/401. Length L2 does not represent the length of a guidewire lumen, but the length of the portion that connects a tube forming a guidewire shaft, which contains a guidewire lumen, to the tube forming a main shaft, which can comprise for example an aspiration lumen. Also in both cases, the length L1 is defined as the length of the obliquely curt portion of the main shaft 301/401. (*See, Specification, Fig. 3 and 4; pg. 7, line 20 – pg. 8, line 23*)

It is a discovery of the present invention that an advantage is obtained by how the selection of L1 and L2 relate to each other. Specifically, not only do L1 and L2 need to be chosen to be within the optimal ranges of 2 mm to 10 mm and 1 mm to 15 mm, respectfully; L1 and L2 need to be chosen so that both the relationships $0.5 \leq L2/L1$ and $L2 - L1 \leq 5$ mm are satisfied.

Table 1 of the Specification shows the different bonding strengths and trackabilities that occur for different values of L1 and L2. Table 1 depicts this discovery of the present application that L1 and L2 cannot be chosen to merely be within an optimum range of values. This requirement is evidenced by, Examples 4 and 5 and Comparative Examples 3 and 4 shown Table 1. All four entries have the same value for L1, 10 mm, and different values for L2. Examples 4 and 5 have values for L2 that not only fall within the optimum range of 1 mm to 15 mm, but also satisfy the relationships $0.5 \leq L2/L1$ and $L2 - L1 \leq 5$ mm. Both of these examples are shown to have a good bonding strength and satisfactory trackaility. However, in Comparative Example 4 L2 is chosen to be 20 mm and outside the optimum range which results kinking in the catheter and unsatisfactory trackability. In Comparative Example 3 L2 is chosen to be 2 mm, within the

optimum range; However in this embodiment, while L2 – L2 = -8.0 mm and satisfies one of the required relationships, L2/L1 = 0.2 and does not satisfy the other relationship. The resulting catheter has a low bonding strength of 2.9 N and an unsatisfactory trackability. Additionally, Comparative Example 2 shows an embodiment where L1 = 2 and L2 = 10, which again fall within the respective optimum ranges for L1 and L2, however in this case L2/L1 = 5 and L2 –L1 = 8.0 mm and do not obey the required relationships. In this example the catheter did have a high bonding strength of 11.5 N, but kinking occurred in the catheter and as such the catheter is unsatisfactory. As shown by the table even if the length difference between L1 and L2 is pretty small, the effect such as bonding strength and trackability are still largely different. The above relationships between L1 and L2 ($0.5 \leq L2/L1$ and $L2 - L1 \leq 5$ mm), are critical for the present invention. If these relationships are not maintained, catheters with unsatisfactory characteristics result, even if the lengths chosen for L1 and L2 fall within optimal ranges. (*See, Specification, Table 1; p. 9, lines 9 – 25*)

The Office Action asserts that the Zadno-Azizi main shaft 282 and guidewire lumen 284, as depicted in Fig. 14, discloses the present invention. As discussed above and conceded by the Office Action, Zando-Azizi discloses that the guide wire lumen 286 is set at 5 cm to 30 cm (50 mm to 300 mm). However, defining a range for the length of a lumen does not teach or suggest the length L2 of a connecting portion of a guide shaft, which contains the lumen, that connects the guide shaft to a main shaft.

The Office Action also concedes that Zadno-Azizi does not teach or suggest the relationship "$L2 - L1 \leq 5$ mm".

Keown is cited by the Office Action to remedy the deficiencies of Zadno-Azizi, as Keown shows different guidewire lengths in Figs. 9A to 9E. However, as discussed above Keown discloses a catheter 5 with a separate distal tip 45 that is

attached to the end tip of the catheter 5. While, each of the embodiments depicted in Figs. 9A to 9E depict a guidewire lumen 50 (which can be 0.75 cm long) that is a part of a distal tip 45, they also depict a portion that is used to connect the distal tip 45 to the catheter 5 (for example the staked pin 80 in Fig. 9B). However, no information regarding the entire length of this portion nor what specific length L2 of this portion is required to actually connect the distal tip 45 to the catheter 5.

Even assuming arguendo that the Zando-Azizi combined with Keown references teaches a lumen, as taught by Zando-Azizi Fig. 14 that can be between 0.75 cm and 30 cm, the cited references still fail to teach or suggest the claimed invention as defined by amended claim 1.

Applicants respectfully submit that teaching the possible length of a lumen can be between 75 mm and 300 mm does not teach or suggest a length L2 of a shaft that contains the lumen, which is used to connect the lumen to a catheter, where the length L2 falls between 1 mm to 15 mm.

Moreover, Zadno-Azizi remains silent regarding any specific length L1, where L1 is the length of the obliquely cut portion of the main shaft of a catheter in the longitudinal direction of that catheter. Keown also fails to disclose any information regarding the longitudinal length of an oblique portion of a catheter tip. Without disclosing any specific criteria for the selection of the longitudinal length of an obliquely cut portion (L1) the cited references fail to teach or suggest that L1 can fall between 2 mm and 10 mm.

For this reason, it also cannot be said that the cited references teach any relationship between the values chosen for L1 or L2. For example, the citied references cannot be said to teach or suggest that L1 and L2 satisfy the relationships that $0.5 \leq L2/L1$ and $L2 - L1 \leq 5$ mm. As discussed above these relationships between L1 and L2 are not the results of, as suggested by the Office Action, mere routine experimentation.

Accordingly, Zando-Azizi and Keown fail to teach or suggest an aspiration catheter comprising "the tip of the main shaft is obliquely cut, the distal end of the guidewire shaft is positioned at the distal end of the main shaft or protrudes from the distal end of the main shaft in the distal direction, and the relationships 2 mm $\leq$ L1 $\leq$ 10 mm, 1 mm $\leq$ L2 $\leq$ 15 mm, 0.5 $\leq$ L2/L1 and L2 - L1 $\leq$ 5 mm are satisfied, wherein L1 is the length of the obliquely cut portion of the main shaft in the longitudinal direction of the catheter, and L2 is the length from the proximal end of the guidewire shaft to the distal end of the main shaft", as required by amended independent claim 1.

As discussed above the ancillary references Sepetka and Weaver, fail to remedy the above deficiencies of Zadno-Azizi and Keown.

Since the applied references fail to disclose, teach or suggest the above features recited in amended independent Claim 1, these references cannot be said to anticipate or render obvious the invention which is the subject matter of that claim.

Accordingly, amended independent Claim 1 is believed to be in condition for allowance and such allowance is respectfully requested.

The remaining claims depend either directly or indirectly from independent Claim 1 and recite additional features of the invention which are neither disclosed nor fairly suggested by the applied references and are therefore also believed to be in condition for allowance and such allowance is requested.

Conclusion

In view of the foregoing, it is respectfully submitted that the application is in condition for allowance. Reexamination and reconsideration of the application, as amended, are requested.

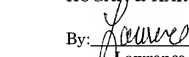
If for any reason the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles, California telephone number (310) 785-4721 to discuss the steps necessary for placing the application in condition for allowance.

If there are any fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1314.

Respectfully submitted,

HOGAN & HARTSON L.L.P.

Date: January 31, 2007

By: 

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